

Phone: 201-599-0325
Fax: 201-599-0338

Jaffer

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Fax

To: **Lyle Jaffe**

From: **Robert Cohen**

Fax: 301-827-6870

Date: October 27, 1999

Phone: 301-827-6869

Pages: 2

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Re: Docket No. 99P-4613

Dear Mr. Jaffe,

Here are all of the references that FDA should consider in my Citizen's Petition.
Please add this to the file (Docket No. 99P-4613).

Thank you,

Robert Cohen

99P-4613

SUP 1

Recent scientific evidence supports a conclusion that the consumption of milk from cows treated with recombinant bovine growth hormone (rbGH) poses a serious health risk to milk and dairy consumers.

The Food & Drug Administration (FDA) published a review of the controversy surrounding rbGH and, in doing so, concluded that the bovine growth hormone produced no metabolic effect in humans and is, therefore, no cause for concern.¹ That conclusion was based upon two principles. First, FDA cited a pasteurization study in which they concluded that 90% of the bovine growth hormone was destroyed by heat treatment. In fact, that study revealed that only 19% of the bGH was destroyed, and that was accomplished by exposing milk to an exaggerated heat-treatment protocol. During pasteurization, milk is traditionally treated for 15 seconds at 162°F. The study in question treated milk at 162°F. for 30 minutes, not 15 seconds.² Furthermore, FDA concluded that there was no basis for concern, assuming that protein hormones are digested in the stomach and gastrointestinal tract.¹

FDA accepted the fact that the manufacturing process for Monsanto's version of rbGH did not produce an exact duplicate of the naturally occurring bGH, citing a study in which the N-terminus of rbGH was incorrectly transcribed as methionine. In that citation, Jerome Moore revealed that the end amino acid would not produce a significant change in a protein, but warned that a different amino acid in the middle of the sequence of a protein chain could have significant consequences, quite often disastrous.³ Monsanto had actually discovered that a "freak" amino acid was created in the #144 position (of the 191 amino acid chain of rbGH) but withheld that information from FDA until after rbGH was approved.⁴ Although Monsanto "fixed" this error, such an admission invalidated seven previous years of research in which rbGH with a "freak" amino acid was administered to laboratory animals.

In approving rbGH, FDA concluded that "wholesome milk" and genetically engineered milk were indistinguishable. In assessing the safety of the new milk, the *Journal of the American Medical Association* supported that incorrect conclusion.⁵ The abstract of FDA's *Science* paper and studies cited within that publication support the conclusion that levels of insulin-like growth factor-I (IGF-I) increase in milk from rbGH-treated cows.¹

The bovine growth hormone and its genetically engineered version both contain 191 amino acids. Human growth hormone also contains 191 amino acids. The gene sequence between the two species differs, however, by a factor of 35%. IGF-I in humans and cows contains 70 amino acids and the gene sequence is identical.¹ IGF-I has been called a key factor in prostate cancer,⁶ breast cancer,⁷ and lung cancer.⁸

New evidence published in the *Journal of the American Dietetic Association* indicates that "serum IGF-I levels increased significantly in the milk group...an increase of about 10% above baseline-but was unchanged in the control group."⁹ The conclusion that hormones contained in milk do not survive digestion has been incorrectly applied to the approval of rbGH. Science has ignored a general principle and universal wisdom applied to all mammals. Milk is a hormonal delivery system. Mechanisms in milk insure that lactoferrins, immunoglobulins, and protein hormones do indeed survive digestive processes, and exert biological effects. Mankind might very well wake up in the 21st century and respond to the GOT MILK query with this conclusion supported by the most recent scientific observations: GOT CANCER.

¹ Judith C. Juskevich and C. Greg Guyer. "Bovine Growth Hormone: Human Food Safety Evaluation." *Science*, vol. 249. August 24, 1990, pp. 875-884.

² P.P. Groenewegen, B.W. McBride, J.H. Burton, T.H. Elasser. *J. Nutr.* 120, 514 (1990).

³ Jerome A. Moore, et al. "Equivalent Potency and Pharmacokinetics of Recombinant Human Growth Hormones with or without an N-Terminal Methionine." *Endocrinology* 122. 1998, pp.2920.

⁴ B.N. Violand, et al. "Isolation of *Escherichia coli* synthesized recombinant eukaryotic proteins that contain epsilon-N-acetyllysine." (Animal Sciences Division, Monsanto Corporation, St. Louis, Missouri.) *Protein Sci.*, 1194 July 3, 1994, pp. 1089-1097.

⁵ Daughaday & Barbano. "Bovine Somatotropin supplementation of dairy cows, Is the Milk Safe?" *JAMA*, 264(8), August 22, 1990, pp. 1003-1005.

⁶ Chen. *Science*, vol. 279. January 23, 1998, p. 563.

⁷ Hankinson. *The Lancet*, vol. 351. May 9, 1998, p. 1393.

⁸ Yu. *Journal of the National Cancer Institute*, vol. 91, no. 2. January 20, 1999.

⁹ Robert P. Heaney, et al. "Dietary changes favorably affect bone remodeling in older adults." *Journal of the American Dietetic Association*, vol. 99, no. 10. October 1999, pp. 1228-1233.